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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/671,524 | 09/27/2000 | Brian G. Scrivens | P-5016 | 6700 |

7590 03/03/2004
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EXAMINER

STOCK JR, GORDON J

ART UNIT PAPER NUMBER

2877

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,524

Applicant(s)

SCRIVENS ET AL.

Examiner

Gordon J Stock

Art Unit

2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2003 has been entered.

Claim Objections

2. **Claims 3-4, 10-13** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As for **claims 3-4**, "the moat surrounding the sample chamber ..." does not further limit the parent claim, for this limitation limits the apparatus rather than the method. As for **claims 10-13**, the limitation of "a plurality of notches ..." limits the apparatus rather than the method. Examiner suggests rewriting the claims in order to give the limitations criticality in regards to the method steps rather than the apparatus. Corrections are required.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 1-13 and 18-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nason (4,790,640)**.

As for **claims 1-13 and 18-23**, Nason in a laboratory slide discloses the following: a sample chamber, a laboratory slide, comprising: two containment walls, a lower transparent slide plate and a cover slip; at least one wall for holding said containment walls at a distance formed from the bonding agent; a separation wall comprising at least a first separation channel and a second separation channel whereas the separation wall consists of a recess and the intersection of two walls making up passages of 150 and 151 of Fig. 8 wherein there is a first and second compartment; a sample entrance; depositing a liquid sample into the entrance; allowing flow; allowing the sample to advance to the separation wall and channels; allowing the sample to continue to advance until it reaches and stops at the end of the sample chamber; obtaining a liquid sample forming a monolayer of cells or particles due to the bonding agent having a thickness equivalent to monocellular thickness (Fig. 8, col. 7, lines 40-67; col. 4, lines 20-40). The sample may be blood (col. 1, lines 15-20). As for venting for the Figure 8 embodiment, Nason is silent; however, Nason teaches that venting means enhances the capillary drawing of the slide (col. 5, lines 1-10). Therefore, it would be obvious to one skilled in the art at the time the invention was made to have venting means in order to enhance the capillary action of the sample chamber. As for the moat and notches limitations, see objections above. The moat and notches are limitations of the apparatus; thereby, not further limiting the method claim because they lack criticality again because they further limit the apparatus and not the method for obtaining a liquid sample forming a monolayer of desired cells.

As for the particular dimensions, the thickness maybe .001 inches or less (col. 4, lines 30-35). As for the other dimensions of the channels and the compartments, Nason is silent. However, Nason's slide produces monolayers, for the thickness between the slide plate and

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coverslip produced by the bonding agent is the thickness of a monocellular layer (col. 4, lines 30-35). Thereby, the sizes of the compartments and the channels in Nason's slide are sufficient to produce a monocellular layer; thereby, being functionally equivalent to applicant's dimensions, for both systems form monolayers. Therefore, it would be obvious to one skilled in the art at the time the invention was made to have Nason's slide comprise the specific dimensions as claimed by the applicant, for Nason's slide forms monolayers. In addition, a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

5. **Claims 1-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guirguis (6,106,483)**.

As for **claims 1-13 and 18-23**, Guirguis in an apparatus for obtaining a cytology monolayer discloses the following: providing an apparatus comprising: a sample chamber, two containment walls; at least one wall for holding containment walls at a distance and enclosing an interior space; a separation wall comprising a plurality of channels, a porous polycarbonate membrane; a first and second compartment; a sample entrance; a means for venting the sample chamber during filling; depositing a liquid sample into sample entrance; allowing sample to flow from entrance to first compartment; allowing sample to advance to separation wall and separation channels of membrane; allowing sample to continue to advance until it reaches and stops at the end of the sample chamber; obtaining a liquid sample forming a monolayer of desired cells. (Figs. 7 and 8; col. 6, lines 30-67; col. 7, lines 1-67; col. 8, lines 1-30). Venting means are disclosed (col. 6, lines 10-15; col. 7, lines 25-30). The moat and notches are limitations of the apparatus; thereby, not further limiting the method claim because they lack

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criticality again because they further limit the apparatus and not the method for obtaining a liquid sample forming a monolayer of desired cells.

As for dimensions, Guirguis discloses the pore size and therefore channel size as .22 microns to 8 microns or 1 to 6 microns for the first porous region; 5 to 60 microns, 15 to 45 microns for the second (col. 6, lines 40-55). As for the other dimensions of the channels and the compartments, Guirguis is silent. However, the dimensions of Guirguis's system are sufficient to produce a monolayer of cells; thereby, being functionally equivalent to applicant's dimensions, for both systems form monolayers. Therefore, it would be obvious to one skilled in the art at the time the invention was made to have Guirguis's system comprise the specific dimensions as claimed by the applicant, for Guirguis's system forms monolayers. In addition, a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

The fluid obtained may be blood (col. 6, lines 4-6). As for the one transparent wall, Guirguis discloses that one containment wall comprises a collection cup (Fig. 8, col. 7, lines 5-10). Examiner takes official notice that collection cups are well known in the art for being transparent in order to visually identify the particular fluid being obtained. Therefore, it would be obvious to one skilled in the art at the time the invention was made that the collection cup was transparent in order to provide visual indication of the particular biological fluid being obtained.

As for **claims 14-17**, Figs. 7 and 8 suggest that the porous membranes comprise notches (46a and 46b of Fig. 7) that transverse the chamber.

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Response to Arguments

6. Applicant's arguments with respect to **claims 1-23** have been considered but are moot in view of the new ground(s) of rejection.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and

2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

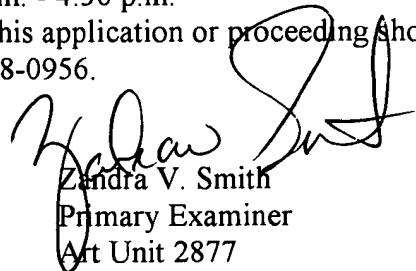
Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (703) 872-9306

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.


gs

February 17, 2004


Zandra V. Smith
Primary Examiner
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